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Dockets Management Branch (HFA-305)
FDA
12420 Parklawn Drive
Room 1-23
Rockville MD 20857

7533 '99 JUL -9 A10 :06

Dear Sir or Madam:

Re: Senokot as a laxative in chronic constipation

Our child, like most others with a Cloacal malformation, suffers from Chronic Idiopathic constipation.

She is currently on a daily dose of 13.4 ml of liquid **Senokot (senna)** which is absolutely necessary for her to have a bowel movement everyday. She has been on this regimen for about 2 years now without any problems. Attempts at increasing dietary fiber have failed to produce the desired results.

We were on the FDA web site recently and came across the May 21, 1998 Federal Register documents concerning the possible restriction on the use of Senokot laxatives.

There exists an organization called the "Pull-Thru Network" established by the families of children with cloaca and anorectal malformations of which we are also members. Many of the children in the Network are on chronic Senokot like our child.

We are in the process of trying out alternative laxatives for our child. Milk of Magnesia is not an option since she has renal impairment which maybe the case with many children with cloacal malformations. We are not comfortable with Lactulose for fear of interference with protein metabolism in a growing child. We have not been able to obtain enough information on Sorbitol use in children and would appreciate it if you could provide or direct us to the same though, we have tried up to a 30cc dose of sorbitol with no results. We are not sure if a higher dose would work and it is very hard to get a child to drink such an enormous amount of an unpleasant tasting solution as a part of their daily routine. Miralax, the new laxative, as you must be aware is not currently indicated for children nor for chronic use.

The final resort in such patients who cannot achieve a good bowel movement through pharmacological adjuncts is a regimen of DAILY ENEMAS FOR LIFE. Again, this is only if laxatives fails. There are currently a lot of children who are well maintained on daily regimen of Senna.

As the well-being and quality of life of my child and I am sure, similar other children, is **dependent on Senokot**, we would greatly appreciate if the FDA takes the measures necessary before reclassifying Senokot; since, the non-availability of Senokot would have a devastating impact on their quality of life in the absence of a tried, effective alternative.

Sincerely,


Mohsin M Hisamuddin


Seema M Hisamuddin

Cc: Gerald M Rachanow, CDER, HFD-560, FDA.

78N-0362

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